Attachment #10

The purpose of this study was to evaluate the potential of the PMN substance to alter the structure of segregation of chromosomes by causing acentric fragments (chromosome fragments lacking a centromere) or whole chromosomes that do not migrate with the other chromosomes during the anaphase of cell division. In either case, micronuclei (small membrane bound DNA fragments) form in the cytoplasm of interphase cells. The study was conducted in accordance with OECD Guideline 487 (In vitro mammalian cell micronucleus test).

Cells were exposed for 4 and 24 hours without metabolic activation (S9 mix) and for 4 hours with S9 mix. Doses ranted from 5 to 200 micrograms/ml.

Precipitation of the PMN substance occurred at 200 micrograms/ml. Cytotoxicity was not seen with 4 hour exposures at doses up to 200 micrograms/ml, but did occur at 200 micrograms/ml for 24 hours. No increase in the number of cells with micronuclei was seen with treated cells. The study director concluded that no indications of a genotoxic effect were observed in the assays at concentrations up to the concentration at which the PMN substance precipitated.